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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/554,167 07/11/00 GICQUEL

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HM12/1107

EXAMINER

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ART UNIT PAPER NUMBER

1641

DATE MAILED:

11/07/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/554,167

Applicant(s)

GICQUEL ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. EP 0837331 has not been considered, as it is not in the English language and a statement of relevance has not been included in the specification.

Drawings

2. The subject matter of this application admits of illustration by drawings to facilitate understanding of the invention. Applicant is required to furnish drawings under 37 CFR 1.81.

No new matter may be introduced in the required drawings.

3. Formal drawings are required in this application because none have been provided with the application. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. For examination purposes, the drawings from PCT/FR99/02170 have been used.

Claim Objections

4. Claims 1-14 are objected to because of the following informalities: the numbering of the claims is improper. The claims should be numbered as "1)" or "1." etc. for all the claims instead of "1/".

5. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 is an apparatus claim with a process limitation. As the limitation does not specify a further limitation of the apparatus, the claim does not further limit the parent claim.

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6. Claim 14 is objected to for reciting "a reaction vessel" in line 2 of the claim. This should be changed to "the reaction vessel".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The term "substantially" in claim 3 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how planar the zone is that applicant is claiming.

10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of

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the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation “a photometric detector”, and the claim also recites “a photomultiplier” which is the narrower statement of the range/limitation.

11. Claim 10 recites the limitations “the moving equipment” and “the shutter” in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 11 recites the limitations “the dark chamber”, “the photometric means”, and “the light-tightness testing source”. There is insufficient antecedent basis for this limitation in the claim. In addition, it is unclear what the limitation “illuminating, on command, the outside of the dark chamber” means. If the shutter is closed, how is the outside of the dark chamber illuminated? The sample within the chamber can be illuminated by the photodetector, but what light source is available to illuminate the outside of the chamber, which can be interpreted as meaning outside the shutter, as well.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-2, 4, 7, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uzan et al. (US Pat. 5,849,247) in view of Berthold et al. (US Pat. 5,048,957) and Smethers et al. (US Pat. 5,643,535).

Uzan et al. teaches an automatic immunological assay comprising reaction wells, means for supporting samples to be analyzed, means for supporting reagents, means for taking determined quantities of samples and of reagents and depositing them in reaction wells, means for reading assay results, and means for displacing the wells (col. 1). The reference also teaches means for washing or rinsing the beads in the vessels (col. 2). Furthermore, the reaction modules are formed as single pieces by molding plastics, each comprising eight reaction wells (col. 3). In

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addition, the reference also teaches the use of a pivoting arm that is used to position reagents or samples (col. 5). A substrate specific to a specific enzyme in the reaction well is deposited in the well, and enzyme interaction takes place, which is followed by reading of the results (col. 7).

Uzan et al. also teach horizontal plates for receiving or supporting the washing means and photometric means. The reference does not teach the specific use of vessels with opaque sides or a chemiluminescent substance as the enzyme in the reaction well.

Berthold et al. teach a specimen rack made of radiopaque material, such that each cuvette, except for a region defined by the lower opening cross section of the through chambers and their upper filling opening, is continuously shielded from scattering radiation from adjacent cuvettes (abstract). The reference does not teach the use of a chemiluminescent substance.

Smethers et al. teach a luminometer with reduced sample crosstalk comprising an array of sample wells, a photodetector assembly, and means for moving the sample tray and photodetector (abstract). Each well in the array has a structure defining a window through which light can be emitted (col. 2). The reference also teaches the use of luminescence, either chemiluminescence or bioluminescence, as an effective for the determination of a variety of analytes (col. 1). Smethers et al. also teach a photodetector internal-calibration system. This includes a sealed chamber with a light source contained therein, a photosensor, and means for directing the light emitted from the light source to the photodetector when the assembly is positioned at an internal calibration system station. In addition, the reference teaches an external calibration system (col. 2).

It would have been *prima facie* obvious to one of ordinary skill at the time of the invention to use the opaque vessel of Berthold et al. and the chemiluminescent label of Smethers

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et al. with the vessel of Uzan et al. One would have been motivated to use a chemiluminescent label with the vessel of Uzan et al. because they teach the generic use an enzyme specific for a substrate that produces a detectable signal. Chemiluminescent labels are widely used for this purpose, and would have been an obvious choice for use in the vessel. In addition, one would have been motivated to use a vessel or well with opaque sides to reduce the cross talk or contamination of reading between cells. Since opaque sides limit the emission of light to the top-filling opening, other wells will not be contaminated with the results of adjacent wells.

17. Claims 3, 5-6, and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uzan et al. (US Pat. 5,849,247) in view of Berthold et al. (US Pat. 5,048,957) and Smethers et al. (US Pat. 5,643,535) as applied to claims 1-2, 4, 7, and 13-14 above, and further in view of Honzawa et al. (US Pat. 5,637,874).

Honzawa et al. teach a chemiluminescence measuring apparatus comprising a shutter mechanism. The shutter mechanism, when closed, will create a temporary dark chamber that is proof against external light, at which time the photodetector will measure the luminescence. Furthermore, the shutter mechanism includes a rotating hollow chamber, which houses the vessel, a dark box, which can be interpreted as a light-proof shoe, that encompasses the read window, and a photosensing unit, which includes a photomultiplier (col. 2). The rotation of the cylindrical member determines when the shutter opens and closes, and correspondingly when the luminescence is measured. In addition, the dark box portion of the light-proof shoe has an opening that creates an optical path between the vessel and photometric means (col. 2).

It would have been *prima facie* obvious to one of ordinary skill at the time of the invention to use the shutter mechanism and light-proof shoe of Honzawa et al. with the modified

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vessel of Uzan et al. One would have been motivated to use the shutter mechanism to create a temporary dark chamber to obtain a luminescence reading. Furthermore, a shutter mechanism is well-known in the art, as the majority of commercially available photometry instruments utilize these mechanisms to take luminescence readings. In addition, a light proof shoe can be interpreted as any enclosure or part that is impermeable to light. Once again, this is well known in the art, as all photometers utilize this technique. It would have been obvious to use the calibration system of Smethers et al. with the modified device of Uzan et al. in order to ensure accurate readings for the samples. Calibration is also well known in the art, as background readings need to be subtracted to get true luminescence readings. As Claim 12 is an apparatus claim, the process limitation recited therein receives no patentable weight, and is therefore rejected along with claim 11, as no further apparatus limitation is recited.

Conclusion

Claims 1-14 are rejected.

References: Anderson, Leistner et al., Bernstein et al., Eberly et al., Lundblom, Matte, Carey et al., Ginsberg et al., Choperena et al., Sanz et al., Wood et al., Wakatake et al., Uzan et al., Whitehead et al., Palmer et al., Hayashi et al., Yamashita et al., and Kusnetz are cited as art of particular relevance to the claimed invention, but are not relied upon in this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4243 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



November 6, 2000



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